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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,053	07/15/2003	Peter G. Bakhit	17566 (AP)	8806

7590 10/14/2004

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,053	BAKHIT ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-18,20-27 and 29-53* is/are rejected.

7)☒ Claim(s) *9,19 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20031015*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

2. Claims 1, 6, 20, 25, 29, 30, and 35-38 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by the WO Patent Application 02/085402. The WO Patent Application '402 teaches aqueous rinse or spray solutions comprising a trefoil peptide, a mucoadhesive, and an anti-inflammatory agent. The trefoil peptide can be TFF1, TFF2, or TFF3, and trefoil peptide concentrations range from 0.1-100 mg/ml. The mucoadhesive can be an oligosaccharide or polysaccharide, including cellulose derivatives, chitosan, pectin, and gellan. See, e.g., page 8, lines 1-16; page 11, lines 6-29; page 15, lines 6-11; and page 17, lines 22-25. It should also be noted that the water which is present in the aqueous solutions of the WO Patent Application '402 is also a mucoadhesive as defined by Applicants. Applicants define "mucoadhesive" at page 5, lines 15-19, as being a component, which can be natural, which adheres to a subject's mucous membrane such as by hydrogen bonding and Van der Waal forces. Water is a natural component which will bind at least to the polysaccharide components of a mucous membrane at least by hydrogen bonding. Note that an intended use limitation does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art. With respect to instant claim 20, because of the liquid nature of the aqueous rinse or spray solution of the WO Patent Application '402, inherently the solution of the WO Patent Application '402 will be present in some type of container, which satisfies Applicants' claim requirement for a package. With respect to Applicants' claim limitations that the use of the composition for the prevention or treatment of dry eye be indicated on the container or that the composition be indicated for topical opthalmic use in the treatment of dry eye, the content of the instructions in a kit claim does not impart novelty where the kit is otherwise taught by the prior art. In re Ngai, 70 USPQ2d 1862 (CAFC 2004).

3. Claims 2-5 and 21-24 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 02/085402. Application of the WO Patent Application '402 is the same as in the above rejection of claims 1, 6, 20, 25, 29, 30, and 35-38. The WO Patent Application '402 does not teach Applicants' claimed trefoil peptide concentrations. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal trefoil peptide concentrations for the WO Patent Application '402 because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

4. Claims 1, 6, 10, 16, 20, 25, 37, and 38 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Thim et al (U.S. Patent Application Publication 2003/0032585). Thim et al teach pharmaceutical compositions comprising TFF2 peptides. The compositions can be aqueous. The compositions can comprise a mucin glycoprotein. The compositions can be used to treat dry eyes. See, e.g., paragraphs [0051], [0077] - [0083], [0133], [0173], and claims 8, 21-23, 30, and 49. The water which is present in the aqueous solutions of Thim et al is a mucoadhesive as defined by Applicants. Applicants define "mucoadhesive" at page 5, lines 15-19, as being a component, which can be natural, which adheres to a subject's mucous membrane such as by hydrogen bonding and Van der Waal forces. Water is a natural component which will bind at least to the polysaccharide components of a mucous membrane at least by hydrogen bonding. The mucin glycoprotein of Thim et al also satisfies Applicants' claim requirement for a mucoadhesive, because a mucin glycoprotein will inherently bind at least to the polysaccharide components of a mucous membrane at least by hydrogen bonding. With respect to instant claim 6, 16, 25, and 37, one or the other of the water and the mucin glycoprotein of Thim et al

corresponds to Applicants' second therapeutically active agent. The claims do not exclude the possibility that the second therapeutically active agent can also be a mucoadhesive, and do not exclude the possibility that more than one mucoadhesive can be present.

5. Claims 2-5, 12-15, and 21-24 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0032585). Application of Thim et al is the same as in the above rejection of claims 1, 6, 10, 16, 20, 25, 37, and 38. Thim et al do not teach Applicants' claimed trefoil peptide concentrations. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal trefoil peptide concentrations for Thim et al because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

6. Claims 6, 7, 16, 17, 25, 26, and 37-53 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0032585) as applied against claims 1, 6, 10, 16, 20, 25, 37, and 38 above, and further in view of Kaswan (U.S. Patent No. 4,839,342), Pendergast et al (U.S. Patent No. 6,348,589), Yerxa (U.S. Patent No. 6,277,855), Gilbard (U.S. Patent No. 6,432,934), Pflugfelder et al (U.S. Patent No. 6,153,607), Pflugfelder et al (U.S. Patent No. 5,652,209) or Sullivan (U.S. Patent No. 6,107,289). Thim et al do not teach including another therapeutically active agent such as cyclosporin A, a nucleotide purinergic receptor agonist, a nicotinic receptor agonist, a tetracycline or a derivative or analogue thereof, or a chemically modified tetracycline, a corticosteroid, a product of human lacrimal gland acinar epithelia, or an androgen or an analogue thereof, with their compositions for treating dry eye. Kaswan teaches the administration of cyclosporin A to treat dry eye (see, e.g., column 1, lines 8-15, and column 6, lines 36-57). Pendergast et al teach the administration of dinucleotides such

as P^1,P^4-is(uridine 5') tetraphosphate to treat dry eye (see, e.g., claims 1 and 6). Yerxa teaches the administration of nicotinic receptor agonists such as nicotine to treat dry eye (see, e.g., the Abstract). Gilbard teaches the administration of tetracycline to treat dry eye (see, e.g., the Abstract). Pflugfelder et al '607 teaches the administration of corticosteroids such as methylprednisolone sodium acetate to treat dry eye (see, e.g., the abstract and claims 1 and 2). Pflugfelder et al '209 teaches the administration of transforming growth factor beta to treat dry eye (see, e.g., claims 1 and 2). Sullivan teaches the administration of androgen or androgen analogues such as 4,5α-dihydrotestosterone to treat dry eye (see, e.g., the Abstract; column 1, line 51; and column 3, line 59). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include one or more of the active agents of Kaswan, Pendergast et al, Yerxa, Gilbard, Pflugfelder et al '607, Pflugfelder et al '209, or Sullivan in the compositions of Thim et al for the treatment of dry eye because it is prima facie obvious to use a mixture of two materials each of which has been used separately for the same process (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), and because the use of plural active agents would increase the chances that effective treatment would occur by targeting more than one underlying biochemical cause.

7. Claims 8, 11, 18, and 27 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0032585) as applied against claims 1, 6, 10, 16, 20, 25, 37, and 38 above, and further in view of Saettone et al (U.S. Patent No. 6,056,950). Thim et al teach their compositions in the form of eye droplets for the treatment of dry eye (see, e.g., claims 22 and 23), but do not teach the presence of tamarind seed polysaccharide in the eye droplets. Saettone et al teach the inclusion of tamarind seed polysaccharide in artificial tears for

the treatment of dry eye. The inclusion of tamarind seed polysaccharide results in prolonging the permanence time of active agents introduced by the eye in the artificial tears. See, e.g., the Abstract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the tamarind seed polysaccharide of Saettone et al in the eye droplets of Thim et al because the tamarind seed polysaccharide would have been expected to cause an increase in the duration of action of the TFF2 peptides of Thim et al.

8. Claims 1, 6, 10, 16, 20, 25, 29-32, and 35-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Thim et al (U.S. Patent Application Publication 2003/0153496). Thim et al teach pharmaceutical compositions comprising TFF1 and TFF3 dimer peptides. The compositions can be aqueous. The compositions can comprise a mucin glycoprotein. The compositions can be used to treat dry eyes. See, e.g., paragraphs [0074] - [0076], [0117], and claims 6-8, 22, 23, 33, 34, and 39. The water which is present in the aqueous solutions of Thim et al is a mucoadhesive as defined by Applicants. Applicants define "mucoadhesive" at page 5, lines 15-19, as being a component, which can be natural, which adheres to a subject's mucous membrane such as by hydrogen bonding and Van der Waal forces. Water is a natural component which will bind at least to the polysaccharide components of a mucous membrane at least by hydrogen bonding. The mucin glycoprotein of Thim et al also satisfies Applicants' claim requirement for a mucoadhesive, because a mucin glycoprotein will inherently bind at least to the polysaccharide components of a mucous membrane at least by hydrogen bonding. With respect to instant claim 6, 16, 25, and 37, one or the other of the water and the mucin glycoprotein of Thim et al corresponds to Applicants' second therapeutically active agent. The claims do not exclude the

possibility that the second therapeutically active agent can also be a mucoadhesive, and do not exclude the possibility that more than one mucoadhesive can be present.

9. Claims 2-5, 12-15, and 21-24 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0153496). Application of Thim et al is the same as in the above rejection of claims 1, 6, 10, 16, 20, 25, 29-32, and 35-38. Thim et al do not teach Applicants' claimed trefoil peptide concentrations. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal trefoil peptide concentrations for Thim et al because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

10. Claims 6, 7, 16, 17, 25, 26, and 37-53 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0153496) as applied against claims 1, 6, 10, 16, 20, 25, 29-32, and 35-38 above, and further in view of Kaswan (U.S. Patent No. 4,839,342), Pendergast et al (U.S. Patent No. 6,348,589), Yerxa (U.S. Patent No. 6,277,855), Gilbard (U.S. Patent No. 6,432,934), Pflugfelder et al (U.S. Patent No. 6,153,607), Pflugfelder et al (U.S. Patent No. 5,652,209) or Sullivan (U.S. Patent No. 6,107,289). Thim et al do not teach including another therapeutically active agent such as cyclosporin A, a nucleotide purinergic receptor agonist, a nicotinic receptor agonist, a tetracycline or a derivative or analogue thereof, or a chemically modified tetracycline, a corticosteroid, a product of human lacrimal gland acinar epithelia, or an androgen or an analogue thereof, with their compositions for treating dry eye. Kaswan teaches the administration of cyclosporin A to treat dry eye (see, e.g., column 1, lines 8-15, and column 6, lines 36-57). Pendergast et al teach the administration of dinucleotides such as P^1,P^4-is(uridine 5') tetraphosphate to treat dry eye (see, e.g., claims 1 and 6). Yerxa teaches

the administration of nicotinic receptor agonists such as nicotine to treat dry eye (see, e.g., the Abstract). Gilbard teaches the administration of tetracycline to treat dry eye (see, e.g., the Abstract). Pflugfelder et al '607 teaches the administration of corticosteroids such as methylprednisolone sodium acetate to treat dry eye (see, e.g., the abstract and claims 1 and 2). Pflugfelder et al '209 teaches the administration of transforming growth factor beta to treat dry eye (see, e.g., claims 1 and 2). Sullivan teaches the administration of androgen or androgen analogues such as 4,5α-dihydrotestosterone to treat dry eye (see, e.g., the Abstract; column 1, line 51; and column 3, line 59). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include one or more of the active agents of Kaswan, Pendergast et al, Yerxa, Gilbard, Pflugfelder et al '607, Pflugfelder et al '209, or Sullivan in the compositions of Thim et al for the treatment of dry eye because it is prima facie obvious to use a mixture of two materials each of which has been used separately for the same process (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), and because the use of plural active agents would increase the chances that effective treatment would occur by targeting more than one underlying biochemical cause.

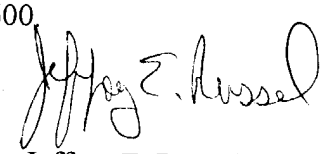
11. Claims 8, 11, 18, 27, 33, and 34 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0153496) as applied against claims 1, 6, 10, 16, 20, 25, 29-32, and 35-38 above, and further in view of Saettone et al (U.S. Patent No. 6,056,950). Thim et al teach their compositions in the form of eye droplets for the treatment of dry eye (see, e.g., claims 22 and 23), but do not teach the presence of tamarind seed polysaccharide in the eye droplets. Saettone et al teach the inclusion of tamarind seed polysaccharide in artificial tears for the treatment of dry eye. The inclusion of tamarind seed

polysaccharide results in prolonging the permanence time of active agents introduced by the eye in the artificial tears. See, e.g., the Abstract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the tamarind seed polysaccharide of Saettone et al in the eye droplets of Thim et al because the tamarind seed polysaccharide would have been expected to cause an increase in the duration of action of the TFF2 peptides of Thim et al.

12. Claims 9, 19, and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The specific combinations and concentrations of additives recited in these claims is not taught or suggested by the prior art of record.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
October 4, 2004